

# **EXHIBIT 43**

1 UNITED STATES DISTRICT COURT  
2 DISTRICT OF MINNESOTA  
3

4 In re Bair Hugger Forced Air ) MDL No. 15-2666  
Warming Products Liability ) (JNE/FLN)  
5 Litigation, ) VOLUME I  
 ) PAGES 1-210  
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13 VIDEOTAPED DEPOSITION OF JONATHAN SAMET, M.D.  
14 LOS ANGELES, CALIFORNIA  
15 TUESDAY, JULY 11, 2017  
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24 Job No. 124786  
25 DORIEN SAITO, CSR 12568, CLR

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1 about the surveillance time in Wansbeck, I thought it  
2 started in October '08. I just -- which is why I had  
3 wondered with that -- somewhere in 2008 with the lower  
4 rates earlier in the year.

5 But in any case, I mean, yes, there's some  
6 variation in this moving average.

7 Q And from a statistical standpoint, you're --  
8 you think that the proper way to analyze these data is  
9 to just say "Well, we'll just" -- "we're just going to  
10 compare the overall average of a twenty-month period  
11 that goes up and down and up to a seven-month period"?

12 A No. Let me say --

13 MS. CONLIN: Well, objection -- objection  
14 as to form in terms of the time.

15 THE WITNESS: Sorry. Forgive me. Just  
16 restate the question for me.

17 MR. GORDON: Well, I don't think it was  
18 accurate. So, Jan, if you want to enlighten me as  
19 to where I -- I misspoke I would be happy to --

20 MS. CONLIN: Well, I --

21 MR. GORDON: -- be educated.

22 MS. CONLIN: -- I can't tell from -- I  
23 don't want to have a speaking objection, but I  
24 think --

25 MR. GORDON: I'm inviting you.

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1 MS. CONLIN: All right. The -- this  
2 chart starts on September 1st, 2007, which we  
3 think the record is pretty clear. And it's an  
4 inaccurate -- inaccurate data set for that. So  
5 that -- that was the issue, but I didn't want  
6 to --

7 MR. GORDON: Okay. No. I'm glad you --  
8 and that's fine. Let's -- I will clarify --  
9 clarify my question then. I wasn't -- that wasn't  
10 what I was intending to ask.

11 Q I'm talking about the twenty-month period  
12 that is depicted in Professor Holford's Figure 2 as  
13 the Bair Hugger study period. There's a red line  
14 across that corresponds to the study time period  
15 reflected in the McGovern paper. And that's a  
16 seven-month period that is identified here as the  
17 HotDog study. Those are -- are the two periods I was  
18 referring to.

19 And you've got twenty months of -- of data in  
20 the Bair Hugger study that go to a low, as you say,  
21 of, it looks like, less than 1 percent to a high of 4  
22 or 5 percent during that twenty months. And then  
23 you've got -- and that's being compared to the average  
24 of seven months of data from McGovern -- or from the  
25 HotDog period.

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1 Do you think from an epidemiological  
2 standpoint that averaging data with that kind of  
3 variability over twenty months and comparing it to a  
4 seven-month period is sound epidemiological  
5 methodology?

6 A Well, yeah, let me comment from a different  
7 perspective. I've done a lot of time series analyses.

8 This data set is simply too small to do any  
9 sort of formal analysis. It's small. It's -- I'll  
10 use the word "noisy." And probably the best way to  
11 get a stable signal is to average the data that is at  
12 hand.

13 Q When you have a small and noisy series,  
14 doesn't that impact the -- the weight that you can  
15 give to any conclusions from it?

16 A Well, again, as I said, the best way to try  
17 to understand what the signal is, is to average all  
18 the data you have and -- and use it all.

19 Q You're saying the best way under adverse --  
20 the -- the less than ideal circumstances of having a  
21 small and noisy data set?

22 A I'm simply referring to the data at hand in  
23 this -- in this picture.

24 Q In your professional work, either your  
25 teaching or if you do health organization bodies like

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1 that, would you recommend a change in practice based  
2 upon a single observational study that has this  
3 limited data set and is this noisy?

4 MS. CONLIN: Objection as to form, it  
5 misstates his report.

6 THE WITNESS: Yeah. Again, my  
7 conclusions as I've -- the conclusion of my report  
8 is not based solely on the McGovern data set.  
9 There's extensive review of other materials.  
10 BY MR. GORDON:

11 Q Yeah, and we're going to -- and I -- and I am  
12 confining my questions to McGovern.

13 So if -- if you take had the McGovern paper  
14 out of your consideration, are you saying that your --  
15 your opinion would remain the same, that the Bair  
16 Hugger is a substantial cause of surgical site  
17 infections, substantial to -- or to periprosthetic  
18 infections?

19 MS. CONLIN: It calls for speculation.

20 THE WITNESS: I -- I -- the only comment  
21 I could make is that there's now a second study,  
22 the Augustine report, with another -- an est- --  
23 another estimate of the risks of this too. That's  
24 I think what I can say at this point.

25 ///

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1 BY MR. GORDON:

2 Q Okay. But what I want to understand is when  
3 you came to the opinion that you offered to the court  
4 on March 30, as I read the report, it -- the McGovern  
5 study is a critical element in how you arrived at your  
6 conclusions. But if I'm -- in fact, that's how I read  
7 it. That doesn't really matter.

8 A Yeah. That's --

9 Q My question to you, because you keep talking  
10 about it -- it's is just part of the data. If you  
11 didn't have the Mc --

12 If you hadn't had the McGovern paper at all,  
13 would you have, based on all the other stuff that  
14 you're talking about, arrived at the same conclusion  
15 on March 30?

16 A The McGovern paper is, at the time I wrote my  
17 report, the sole paper in the peer reviewed literature  
18 offering an estimate of the risk of deep joint  
19 infection associated with the Bair Hugger device.

20 Q So if you hadn't had the McGovern paper, you  
21 would not have reached the conclusions that you  
22 reached --

23 MS. CONLIN: It calls for speculation.

24 BY MR. GORDON:

25 Q -- on March 30; right?

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1 MS. CONLIN: It calls for speculation.

2 THE WITNESS: I -- I could only -- I  
3 could only say that there would not have been  
4 anybody to -- absent the McGovern paper, to  
5 quantify the magnitude of this.

6 BY MR. GORDON:

7 Q Okay. But you would have still opined that  
8 there was a risk, just you couldn't quantify it?

9 A I just can't answer that question.

10 Q Well, let's approach it from a different  
11 standpoint. You've mentioned now several times that  
12 the McGovern paper was not the only evidence or data  
13 upon which you based your conclusion.

14 Tell me what the other body of -- of data is  
15 that contributed to your opinion.

16 A Well, let me take out my report --

17 Q Sure.

18 A -- and -- and comment on that. I think the  
19 sections lay out the different lines of evidence that  
20 were considered and perhaps --

21 Critically the idea is laid out in Figure 3  
22 on page 21.

23 Q Okay. So table -- that table lists four  
24 sentences; right?

25 A No. I said Figure 3 on page 21.

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1 Q Oh, Figure 3. I'm looking at page 3.

2 I'm sorry. What page?

3 A 21.

4 Q Okay. Okay. So you -- this is, you say,  
5 "Mechanisms by Which the Bair Hugger Increases Risk  
6 for Joint Infection"; is that right?

7 A That's the title.

8 Q And you have the first two arrows. One goes  
9 to disturbed unit or directional flow. The other goes  
10 to microbial contamination of a surgical field.  
11 Right?

12 A Correct.

13 Q Let's talk about the bottom, microbial  
14 contamination of a surgical field.

15 What do you mean by "microbial  
16 contamination"?

17 A Microorganisms.

18 Q Okay. And what data did you review that --  
19 well, strike that.

20 Am -- am I correct in inferring from your  
21 depiction here in Figure 3 that you believe there are  
22 some evidence that the Bair Hugger device results in  
23 increased microbial contamination of a surgical field?

24 A Well, it is shown that -- the -- the  
25 literature cited shows that -- and -- and also the

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1 computational fluid dynamics of modeling that there's  
2 increased flow of particles across the surgical field.

3 I believe at least one study -- maybe it's  
4 Moretti [phonetic] -- shows increased numbers of  
5 microorganisms associated with the Bair Hugger  
6 operating and then also the disruption of directional  
7 flow. So those contribute to increased risk of  
8 infection, which is what I've laid out here in  
9 Figure 3.

10 Q You -- you referenced computational fluid  
11 dynamics.

12 I take it you are referring to the  
13 computational fluid dynamics analysis that was done  
14 under contract to Dr. Al Garbashi [phonetic] at the  
15 request of plaintiffs in this case?

16 A That's correct.

17 Q I noticed --

18 MR. GORDON: Let me show you an exhibit  
19 I'm up to 13. Let me show you Exhibit 13.

20 (The aforementioned document was  
21 marked Exhibit 13 for  
22 identification by the reporter.)

23 BY MR. GORDON:

24 Q I noticed in your reference materials you  
25 cited to an unpublished document by Memarzadeh.

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1 And I want to know, first of all, Is  
 2 Exhibit 13 that document to which you were referring?  
 3 MS. CONLIN: I'm sorry. What's the  
 4 question?  
 5 BY MR. GORDON:  
 6 Q Exhibit 13. And take a look at your report  
 7 there. On the reference list is a reference to  
 8 some -- to some unpublished something from Memarzadeh.  
 9 It's your Reference Number 51.  
 10 MS. CONLIN: He's just asking you if  
 11 that -- the reference on there --  
 12 THE WITNESS: Well, I assume so. I'm  
 13 just trying to read from the reference document.  
 14 BY MR. GORDON:  
 15 Q This is -- is Exhibit 13 what you listed as  
 16 Number 51 on your materials considered?  
 17 A Appears to be the case, yes.  
 18 Q So this is something you had --  
 19 Exhibit 13 is something you had available  
 20 before you wrote your report; right?  
 21 A Yes.  
 22 Q And if you turn to page 10 of Exhibit 13 --  
 23 (Witness turning to page.)  
 24 BY MR. GORDON:  
 25 Q -- it says (reading):

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1 "This investigation validates  
 2 the results and conclusions drawn  
 3 by Moretti and others that the  
 4 forced-air warming technology does  
 5 not in and of itself result in  
 6 increased risk of surgical wound  
 7 infection.  
 8 "However, this investigation  
 9 further indicates that if the  
 10 operating room ventilation system  
 11 is designed properly, the  
 12 contaminating particles from staph  
 13 around the patient will not impinge  
 14 on the surgical wound due to  
 15 thermal plume dynamics."  
 16 So that -- you read that before you  
 17 rendered your opinion?  
 18 A (No audible response.)  
 19 Q And -- and we can go through this.  
 20 But what this is, is a computational fluid  
 21 dynamics study; right?  
 22 A Yes.  
 23 Q And staying on page 10, you see that under  
 24 the conflict of interest statement, it says  
 25 "undeclared"?

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1 A I see that, yes.  
 2 Q The CFD, the computational fluid dynamics,  
 3 that -- that you referenced in your report -- or that  
 4 you actually discussed in your report by  
 5 Dr. Al Garbashi, if that were a published paper, you  
 6 would -- you would agree he'd have to declare a  
 7 conflict of interest if that was -- he did that -- he  
 8 was paid by the plaintiff's counsel to do that for  
 9 this litigation?  
 10 A He would have cleared his finances.  
 11 Q Well, don't you think that would be -- would  
 12 constitute a conflict of interest?  
 13 A I -- I think that surmises that funding  
 14 source influences the outcome of this computational  
 15 fluid dynamic model.  
 16 Q Well, okay. Page -- page 10 on the  
 17 Memarzadeh thing identifies the funding sources of the  
 18 National Institutes of Health; right?  
 19 A (No audible response.)  
 20 Q You have to say yes or no.  
 21 A It does, yes.  
 22 Q Okay. But -- so -- and I guess I've seen  
 23 this a lot where there's a conflict of interest  
 24 statement and a funding source statement.  
 25 Is that -- are -- are you saying that there's

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1 view there -- if you declare your funding source,  
 2 that's -- you don't have to declare any conflict of  
 3 interest?  
 4 MS. CONLIN: It misstates his testimony.  
 5 THE WITNESS: No, I didn't say that.  
 6 BY MR. GORDON:  
 7 Q Okay. In fact, I -- the opposite is true.  
 8 Wouldn't you -- wouldn't you agree that it's  
 9 customary to declare funding sources and to identify  
 10 any conflicts of interest?  
 11 A Any potential conflicts of interest, right.  
 12 Q Do you think being an expert witness hired to  
 13 testify on behalf of one side in civil litigation in  
 14 and of itself is a conflict of interest -- a potential  
 15 conflict of interest that would be -- that would  
 16 ordinarily be declared?  
 17 A Well, I -- I think it's clear that the report  
 18 was done for the plaintiffs.  
 19 Q You're talking about Dr. Al Garbashi?  
 20 A Yeah, Dr. Al Garbashi.  
 21 Q I -- for the record, my -- my point is, if it  
 22 had been a -- a paper for use beyond this litigation,  
 23 it would -- you would agree it should probably have a  
 24 conflict of interest disclosure that it was originally  
 25 prepared for litigation?

1 UNITED STATES DISTRICT COURT  
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4 In re Bair Hugger Forced Air ) MDL No. 15-2666  
Warming Products Liability ) (JNE/FLN)  
5 Litigation, ) VOLUME II  
 ) PAGES 211-324  
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13 VIDEOTAPED DEPOSITION OF JONATHAN SAMET, M.D.  
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24 JOB NO. 128394  
25 DORIEN SAITO, CSR 12568, CLR

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1 is, Have you reviewed any materials since we last met  
2 on July 11?

3 A I've refreshed my memory concerning materials  
4 that I have looked at in the past. But with regard to  
5 absolute new materials, no.

6 Q Okay. So you didn't do any additional  
7 research in between July and --

8 A No, I did not.

9 Q -- now?

10 A No.

11 Q And you weren't -- you weren't given any  
12 additional published materials?

13 A No. I simply reviewed materials I had on  
14 hand.

15 Q I'm sorry? Did --

16 A I reviewed materials I already had on hand.

17 Q Okay.

18 MR. GORDON: And -- and we discussed this  
19 a little bit last time. But some of the materials  
20 that you listed on your Exhibit C, if I recall  
21 correctly, of your report, which we marked as  
22 Samet Exhibit 1. I'll give you a copy of it again  
23 just to refresh your recollection.

24 ///

25 ///

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1 (The aforementioned document was  
2 previously marked Exhibit 1 for  
3 identification by the reporter.)

4 BY MR. GORDON:

5 Q But some of those materials were ones that --  
6 well, strike that.

7 All of the materials on Exhibit C in your  
8 report were materials that you had available to you  
9 prior to when you rendered your decision -- your --  
10 your opinion on March 30; correct?

11 A That's right. And then there was the  
12 additional report by Augustine that was --

13 Q Okay. And there -- you know, I don't -- I  
14 don't want to spend a lot of time plowing old ground.

15 But in addition to that Augustine publication,  
16 you, I think, testified that you had read the expert  
17 reports of Holford, Wenzel, Borak. And I --

18 A That --

19 Q And I can't remember -- I apologize.

20 A Right. I'm not sure I can remember.

21 I -- I will add, actually, have read the --  
22 now the deposition of both Drs. Holford and Borak  
23 which were, I think, obtained in the interim between  
24 last month and -- and the -- that -- completion of the  
25 deposition today.

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1 Q Okay. And other than the depositions of  
2 Dr. Holford and Dr. Borak, have you read any other  
3 deposition --

4 A No.

5 Q -- since July 11?

6 Okay. And I can't remember.

7 Had you -- do you recall if you had read the  
8 expert opinion of Dr. Michael Mont?

9 A Offhand, I don't remember, no.

10 Q Okay. And, again, I don't want to replot old  
11 ground. But just -- I want to -- and -- and just so  
12 the record is clear. We talked about it before.

13 MR. GORDON: I want to mark somewhere --  
14 I'm showing you Exhibit 20.

15 (The aforementioned document was marked  
16 Exhibit 20 for identification by the  
17 reporter.)

18 BY MR. GORDON:

19 Q And ask you if this is the Augustine paper  
20 that you said you reviewed.

21 A That's correct.

22 Q And you had reviewed that initially sometime  
23 in between the time you rendered your original opinion  
24 in this case and when you were deposed on July 11;  
25 correct?

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1 A That's -- that's right. My understanding is  
2 the paper was published in -- in the interim following  
3 the preparation of my expert report.

4 Q And since July 11, you've -- you've gone back  
5 and rereviewed this paper; is that right?

6 A Well, I've -- I've refamiliarized myself with  
7 this and other materials.

8 Q Did you review any other materials in  
9 connection with the -- Exhibit 20?

10 A Other materials specifically, no.

11 Q Okay. And nothing about any of the hospitals  
12 that were involved or any testimony of Dr. Augustine or  
13 anything like that?

14 A No, I have not.

15 Q Okay. We'll -- we'll come back to that.

16 You -- and -- and correct me if I'm wrong.  
17 But you have not -- it was not listed on your  
18 Exhibit C, the deposition of Dr. Augustine.

19 So as of March 30, you had not read  
20 Dr. Augustine's deposition?

21 A Not -- not that I recall, no.

22 Q Have you -- and have you read it subsequently?

23 A No.

24 Q Okay. All right. I want to step back and --  
25 we'll pull back about 50,000 feet and just talk about



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1 the -- the scientific process that -- that you have  
2 employed in -- in this case.

3 You -- as epidemiologist, you follow certain  
4 objective approaches to the -- the materials that you  
5 deal with; right? That was a poor -- that was a poor  
6 question.

7 There -- there's -- there's a -- there's a --  
8 there is a methodology that you, as an epidemiologist,  
9 follow in order to arrive at conclusions or opinions  
10 about causal relationships; is that correct?

11 A Well, I guess I would say that my review of  
12 the materials reflects not only my training in  
13 epidemiologist, but in medicine, my broader  
14 understanding of the -- the lung, of air, of movement  
15 of particles in air, things that I've worked on in my  
16 research.

17 So, yes, I -- I interpret the epidemiological  
18 evidence, but I try and put it in the broader context  
19 of biology, clinical path, and physiology, and so on.

20 Q And -- and I -- and I was asking kind of a big  
21 picture question.

22 That's generally how you approach issues of  
23 epidemiology and -- and -- and health-related outcomes;  
24 right?

25 A Yeah.

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1 Q You just don't look at an epidemiological  
2 study. You try to look at other lines of evidence;  
3 right?

4 A Right. I guess I would -- if you'll excuse  
5 me, I would probably rephrase things and say that I  
6 approach questions that are relevant to public health,  
7 population health, and that epidemiology is one of the  
8 research methodologies used to generate evidence that  
9 is relevant to public health.

10 Q In the past, you have been critical of those  
11 who contend that epidemiological studies are prone to  
12 generating false positives; is that correct?

13 A I've been involved in some statements  
14 concerning -- I would say sort of general comments  
15 about epidemiology and the validity of results and how  
16 they may be subject to any number of problems,  
17 including, quote, "false positives."

18 MR. GORDON: Let me show you what's been  
19 marked as Exhibit 21 just to kind of tee this --  
20 tee this up, and we'll plow through it.

21 The aforementioned document was marked  
22 Exhibit 21 for identification by the  
23 reporter.)

24 BY MR. GORDON:

25 Q This is -- this is a paper -- let's say a

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1 commentary that you co-authored in 200- --

2 MS. CONLIN: -9.

3 BY MR. GORDON:

4 Q -- -9; is that right? 200- -- yeah, 2009.

5 A Correct.

6 Q Okay. And this was something that you and  
7 your -- and all -- and the other authors wrote in  
8 response to a publication that was simplistic -- and I  
9 realize I'm being very simplistic. This was  
10 essentially taking the position that observations by  
11 the epidemiological studies are fraught with false  
12 positives.

13 A This was written in response to several --  
14 several papers that posed this sort of too strong  
15 generalization in the view of the author -- co-authors  
16 and myself that there's a generic problem with false  
17 positives, correct.

18 Q And you -- and correct me if I'm wrong. But  
19 you -- part of your opinion is based on your conclusion  
20 that the McGovern paper does not represent a false  
21 positive; is that correct?

22 A Well, the McGovern paper is certainly part of  
23 the evidence that I considered. And to the extent  
24 that the P value is less than .05, that's a helpful  
25 indication that the results are not arrived by chance

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1 alone.

2 And then of course since the McGovern paper,  
3 there's been a second report that essentially  
4 corroborates the -- the findings in other hospitals.

5 Q You're talking about Exhibit -- the Augustine  
6 publication?

7 A Yes, I am. Yes.

8 Q So -- and -- and I -- so specifically my  
9 question with McGovern is, Your opinion is predicated  
10 in -- at least in part on the -- your determination  
11 that the McGovern findings were not -- do not represent  
12 false pos- -- a false positive --

13 A That's --

14 Q -- is that correct?

15 A That's correct, essentially.

16 Q And you -- have you similarly concluded that  
17 the Augustine publication is not based on a false -- or  
18 does -- is -- is not a false positive?

19 A Well, again, yes. And with two papers that  
20 corroborate each other, I think the likelihood that  
21 both are, quote, "false positives" diminishes.

22 And there's -- you know with -- P value is an  
23 assessment of the role of chance. There are other  
24 ways to generate false positives. But with two papers  
25 with quite -- quite similar findings, I think the